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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 15

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Application Number: 09/812,945
Filing Date: March 27, 2001
Appellant(s): LAN-HARGEST ET AL.

Harold H. Fox
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 27,2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. There are no related appeals or interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Claims 1, 2, 4-7, 10, 12, 17-18 and 40-46 are grouped together.

(8) Claims Appealed

The rejection of claims 1, 2, 4-7, 10, 12, 17-18 and 40-46 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(9) Prior Art of Record

Richon et al., "A Class of hybrid polar inducers of transformed cells differentiation inhibits histone deacetylase, " abstract, PMID: 9501205, March 1998.

Marks et al., "Histone Deacetylase Inhibitors." *J of Natl. Cancer Inst.*, Vol. 92 No. 15 (2000), pp. 1210-1216.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-7, 10, 12, 17-18, 40-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some types of cancer, does not reasonably provide enablement for "treating cancer" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Given the current state of the art, the treatment of all cancers broadly is unpredictable. One of ordinary skill in the art would not believe that one compound could treat all types of cancer with a single therapeutic agent. Decisional law would seem to indicate that when the utility in question is sufficiently unusual an examiner is justified in requiring substantiating evidence, *In re Buting*, 163 USPQ 689 (1969). Moreover, one of ordinary skill in the art would not know which cancers could appropriately be treated with the claimed compounds and would be required to perform undue experimentation to determine the effectiveness and suitability of the claimed compounds in the treatment of different types of cancer. The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen.

The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-7, 10, 12, 17-18, 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richon et al. and Marks et al.

Richon et al. teaches that hydroxamic acid derivatives, a class of hybrid bipolar compounds (HPCs) induce terminal differentiation and or apoptosis in various transformed cells, see abstract.

Marks et al. teaches that hydroxamic acid-based HPCs are potentially effective agents for cancer therapy, see abstract (reference FF of IDS).

Richon et al. and Marks et al. do not explicitly teach the elected compound in their method of treating cancer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected compound in a method of treating cancer.

One of ordinary skill in the art would have been motivated to employ the elected compound in a method of treating cancer because the elected compound is a hydroxamic acid derivative. The Skilled Artisan would reasonably expect the elected compound, a derivative of

hydroxamic acid to exhibit therapeutic effects similar to hydroxamic acid because structurally related compounds would have been expected to have similar therapeutic effects.

(11) Response to Argument

The enablement rejection is appropriate because the ultimate goal of the instant invention as set forth in the claims and confirmed by the elected specie, is the treatment of cancer, a histone deacetylase mediated disorder.

Appellant argues that the rejection under 35 USC 112 should be withdrawn because "the treatment of a disorder, and the identity of the disorder, is not the invention being claimed," Brief at 3. Note that independent claim 1 recites "a method of inhibiting histone deacetylase [...] activity in cells, ***thereby treating one or more disorders*** [...]". In the specification Cancer is named as one of the disorders to be treated via the applicant's method. The treatment of all types of cancer (as understood by the generic word cancer) is not enabled by the specification. Also note that the applicant has elected cancer as the disorder to be treated. Note that the ultimate utility of this invention as set forth in the claim is the treatment of a histone deacetylase mediated disorder. Appellant further states that the claimed method requires two actions, i.e., contacting cells with a compound of formula I and determining the level of histone deacetylase in treated versus non-treated cells. Construing the claims in light of appellant arguments would lead the Skilled Artisan to understand and practice the instant method as a screening method, i.e., a method of assaying compounds of formula I to measure their histone deacetylation inhibitory effect. Reading the claim in its entirety and including the phrase "***thereby treating one or more disorders"*** in the claim language, leads the skilled artisan to understand and practice the instant invention as a method of treating histone deacetylase mediated disorders in general and cancer (the elected disorder), in particular.

Appellant further argues that the election of cancer as the specie of histone deacetylase mediated disorder does not limit the scope of claim 1. Note that claim 1 has been examined in so far as it reads on the elected specie of cancer as set forth in the office action of November 6, 2001.

Elucidation of mechanism of action (i.e., histone deacetylase inhibition) does not patentably distinguish the instant claims from the prior art of record.

Appellant also argues against the obviousness rejection stating that none of the cited references teaches a method of histone deacetylation inhibition. The instant claims are directed to effecting a biochemical pathway with known hydroxamic acid derivatives. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by structural differences. The ultimate utility for the class of compounds, hydroxamic acid and its derivatives, is old and well known, rendering the claimed

subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Structural similarity coupled with the teachings of the prior art would provide the requisite motivation to the skilled artisan to modify the prior art and arrive at the instant invention.

Appellant finally argues that neither of the cited references teaches the hydroxamic acid derivatives of formula I. Note that the skilled artisan reasonably expects compounds of similar structured to have the same physiological activities. In fact, similar properties may normally be presumed when compounds are close in structure. *In re Dillon*, 16 USPQ2d 1901, 1904. See also *In re Grabiak*, 226 USPQ 870, 871 (Fed. Cir. 1985). Applicant argues that the claimed invention is non-obvious over the prior art because the exact compounds of formula I (claim 1 herein) are not taught in the prior art references. Note that the both references indicate that the anti-cancer activity as well as the HDAC inhibitory activity of hydroxamic acid compounds are known. Moreover, Marks et al. provides a guide in choosing hydroxamic acid derivatives that would exhibit theses therapeutic activities:

"The essential characteristics of hydroxamic-acid based HPCs are a polar site, the hydroxamic group, a six-carbon hydrophobic methylene spacer, a second polar site and a terminal hydrophobic group" (see page 1212, second column).

Now, consider the following example: compounds of formula I have the two polar sites (i.e., when X1 is an O and when Y1 is O-C(O)-O), the hydroxamic Group is present in formula 1 compounds when X2 is NHOH and X1 is an O, L and Y2 together can form the spacer when L is a 5 carbon chain and Y2 is a CH2, a terminal hydrophobic group is present when A is a benzene ring. Therefore, formula I compounds herein do follow the requirements set forth in Marks et al.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Mojdeh Bahar

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June 12, 2003

Conferees

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